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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,517	05/07/2007	Domokos Boda	9007-1020	3719

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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
12/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,517	BODA, DOMOKOS	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13-17,19 and 20* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's arguments filed 25 September 2008 have been fully considered but they are not persuasive.

Applicant has argued that Salzman's tubes are not in "communicating connection" because they do not physically touch. The Examiner agrees that the tubes do not touch, but communicating connection merely means that there is a connection between the two tubes, which Salzman provides in the form of the chamber. Applicant has not provided a definition of the phrase "communicating connection" which limits it to only a physical connection, and as such it is given its broadest reasonable interpretation. Applicant further argues that there is no motivation for making Salzman's tubes gas-permeable because it already has a gas permeable area; the Examiner disagrees, since increasing the area of gas permeability of the device would make it more efficient. Applicant has also argued that Salzman's lumens are surrounded by a solid catheter and therefore cannot be gas permeable. The Examiner again disagrees; lumens are cavities in a body, in this case the overall catheter 14. By making the catheter of a gas-permeable material, as further described below, the lumens would therefore be exposed to the environment because the tubes which define them - that is, the shaded area in figure 6 - is gas permeable. Applicant further argues that there is no

requirement in Salzman to insert the device to a particular depth, and that because of that there is no reason to fix it in place. The Examiner disagrees. Regardless of the depth of insertion, one would naturally wish for the device to remain fixed rather than moving about, potentially affecting treatment or making the patient uncomfortable. Finally, Applicant has argued that, since Salzman has not specified a tube thickness, it would not have been obvious to choose a thickness. The Examiner once again disagrees. Since Salzman has not called for a particular thickness, it falls to one of ordinary skill in the art to choose a suitable thickness appropriate for the materials in use and the dimensions of the area in which the device will be used. As such, choosing to use the claimed thicknesses would readily be considered a mere matter of design choice by one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

3. Claims 11, 13-17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salzman (US Patent 5423320) in view of Fiddian-Greene (US Patent 6238339).

Regarding claims 11 and 19, Salzman discloses a tonometric device comprising a distal end configured to be inserted in a patient's gastrointestinal tract (element 14) with a section that is introduced into the body (element 14a), where the introduced section comprises a first tube (element 54) that is connected to an additional tube (the portion of 54 remaining outside the body) and parallel to a second tube (element 56) that is also connected to an additional tube (the portion of 56 remaining outside the

body), where the distal end of the first and second tubes are in communication (figure 6), where the tubes are made of gas permeable material (column 5, lines 6-8 and 16-23). Salzman does not disclose the particular gas permeable material, nor means on the external portion of the device for fixing it in position. Fiddian-Greene teaches a tonometric device comprising a sensing section covered with a gas-permeable silicone rubber membrane (column 8, lines 50-51), where the device's position may be fixed using an external component of the device (element 24), in order to effectively control sampling. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Salzman with a silicone rubber tube membrane and means for fixing the device's position, as taught by Fiddian-Greene, in order to effectively control sampling.

Regarding claim 13, Salzman's tubes inherently have connecting means because they are connected to a separate device (column 6, lines 25-27).

Regarding claim 14, Salzman discloses all the elements of the claimed invention, as described above, except for connecting the tubes to a syringe. Fiddian-Greene further teaches tubes that are configured to connect to a syringe (column 24, lines 60-64), in order to manually control pressure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Salzman with the tubes configured to connect to a syringe, as taught by Fiddian-Greene, in order to manually control pressure.

Regarding claims 15 and 16, though Salzman does not expressly disclose the specific diameter and wall thicknesses of the tubes, at the time the invention was made

it would have been an obvious matter of design choice for one of ordinary skill in the art to choose a particular wall thickness and diameter, because the Applicant has not disclose that the particular diameters and thicknesses provide a particular advantage, are for a particular purpose, or solve a stated problem. Moreover, it appears that a particular combination of wall thickness and diameter chosen by one of ordinary skill in the art and Applicant's wall thickness and diameter would perform equally well to monitor a patient.

Regarding claim 17, Salzman's second tube is within the wall surrounding the first tube (figure 6), since the entire shaded structure surrounding the first tube may be considered its wall, thereby making the second tube formed in that wall.

Regarding claim 20, Fiddian-Greene further teaches the gas-permeable material being configured to be permeable for carbon dioxide (column 8, lines 59-67), in order to allow monitoring of a patient's pH. It would have been obvious to one of ordinary skill in the art at the time the invention was made to d have made the device of Salzman and Fiddian-Greene permeable for carbon dioxide, as taught by Fiddian-Greene, in order to allow monitoring of a patient's pH.

Allowable Subject Matter

4. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claim 18, including, *inter-alia*, a tonometric device configured to be inserted into a patient's gastrointestinal tract having first and second gas-permeable tubes in communication with each other at their inserted ends, where the external ends of the tubes are also connected to each other to form a closed system that is filled with an aqueous carbon dioxide detection solution comprising sodium hydrogen carbonate ($NaHCO_3$), sodium chloride (NaCl) and phenolic red (more commonly known as phenol red).

Rantala (US 6432051) discloses using a measuring medium to measure carbon dioxide, but does not disclose the chemical makeup of the solution.

The examiner notes that these ingredients are also commonly found together in Hank's Balanced Salt Solution, but the prior art of record does not disclose using HBSS to detect carbon dioxide.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/

Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735